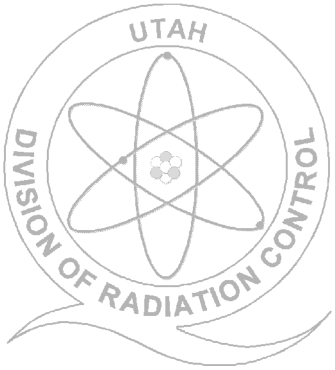
# GUIDELINE FOR THE EVALUATION OF ANGIOGRAPHY & CARDIOLOGY CATH LAB FLUOROSCOPIC X-RAY EQUIPMENT



State of Utah
Department of Environmental Quality
Division of Radiation Control

# GUIDELINE FOR THE EVALUATION OF ANGIOGRAPHY & CARDIOLOGY CATH LAB FLUOROSCOPIC X-RAY EQUIPMENT

## DRC Inspection Program Objective

The overall objective of the Division of Radiation Control (DRC) x-ray inspection program is to reduce the likelihood that individuals will be exposed to unnecessary radiation. In the case of registrants using x-ray equipment in the healing arts, patient exposure is of concern and proper equipment performance is essential. Registrants are required to demonstrate that the equipment satisfies the appropriate regulatory standards for calibration and performance.

## Purpose of Guideline

The intent and purpose of this document is to provide users of **angiography and cardiology cath lab fluoroscopic x-ray equipment** guidelines for the documentation required to demonstrate to the DRC that x-ray equipment satisfies the regulatory standards under clinical use conditions.

## X-ray Equipment Performance and Calibration

The registrant is to document that the following requirements are met.

**1)** Adequate total filtration is present.
**2)** The fluoroscopy timer terminates the exposure or produces an audible signal at the end of a five minute accumulative time interval.
**3)** During fluoroscopy, x-ray field collimation and alignment with the image intensifier (II) is appropriate.
**4)** Fluoroscopic exposure rates do not exceed the regulatory standards.
**5)** Patient exposure information has been obtained for simulated clinical conditions and is posted where it is readily available to the physician during the fluoroscopic procedure.

**The following examples are presented as guidance for what will be considered an adequate evaluation, with support documentation, to demonstrate compliance:**

**1)** Adequate Filtration

For fluoroscopic x-ray equipment with variable added filtration capability, demonstration of adequate filtration shall be accomplished by choosing the filter of least mm aluminum equivalent thickness and showing that the half value layer (HVL) exceeds the minimum regulatory standard. For example, at a measured kVp value of 80, the HVL is to be equal to or greater than 2.3 mm aluminum. This can be demonstrated by:

**a)** Measuring the in air exposure when different thicknesses of aluminum intercept the x-ray beam and determining the HVL value; or

**b)** Measuring the exposure at 80 kVp with and without a 2.5 mm aluminum absorber intercepting the x-ray beam and showing that the ratio of the two exposure values exceeds 0.5.

(Documentation shall include a statement of available filters, the filter chosen for demonstrating adequate filtration, and a listing of measured exposure values and associated thicknesses of aluminum.)

**2**) Fluoroscopic Timer

The fluoroscopy timer terminates the exposure or produces an audible signal at the end of a five minute accumulative time interval.

(Documentation shall indicate that the timer was evaluated and that a conclusion was reached whether the exposure was terminated at the end of five minutes or an audible signal occurred.)

**3)** Fluoroscopic X-ray Field Collimation and Alignment

For fluoroscopic x-ray equipment with variable source to image intensifier distance (SID) capability, the x-ray field is to be aligned with and collimated to the effective field size of the II tube within the regulatory standards for the different SID values that are used clinically. Annual tests are to be carried out to insure that the above condition is met.

(Documentation is available that indicates tests were performed demonstrating that the maximum field size of the x-ray field is confined to the II, for the range of SID values used clinically, within the regulatory standards for the largest effective II size that is available. Evidence of collimation observed on the monitor will be deemed adequate.)

**4)** Limits on Exposure Rates

Exposure rates are to be evaluated to insure that the regulatory limits are not exceeded. Documentation will indicate whether the fluoroscopic unit has a manual mode, automatic brightness control (ABC) mode, pulsed and/or continuous modes of operation, high level control (HLC) mode, the sizes of II available, and if the unit was manufacturer on or before 05/19/95. (NOTE: Different limits apply for units manufactured before and after this date.)

Example 1: A fluoroscopic unit is used in a hospital cardiology cath lab. The unit has three different ABC modes of operation. For all three ABC modes, both the kVp and mA are automatically chosen. During the placement of the catheter, the unit is used in the continuous fluoroscopic mode. However, during cine recording, the unit is used in an ABC pulsed mode at 30 frames per second. It has a nine inch II effective field size. For a given patient, the specific kVp, mA values, and corresponding exposure rate depend on which ABC mode is used and whether the unit is in the continuous or pulsed mode. With a lead absorber intercepting the x-ray beam, the exposure rate is measured at 30 cm from the II, in the fluoroscopic mode which will produce the maximum exposure rate.

(Documentation will indicate the ABC mode used to measure the maximum exposure rate in the continuous mode, the position relative to the II where the measurements were made, the value obtained, and the corresponding kVp and mA values. A statement to the effect that the unit satisfies the regulatory limits, and that the evaluation was adequate to insure that the mode used produced the maximum rate, is to be included.)

## **5)** Patient Exposure Information

The Utah Radiation Control Rules require patient exposure information be readily available to the attending physician during a fluoroscopic procedure. The policy of the Division is that such information is to be available for fluoroscopic units used in the irradiation of either the pelvis, abdominal, or upper GI regions. Information shall be in a format such that entrance skin exposure rates can be readily determined from a knowledge of the fluoroscopic kVp, mA values, and whether the unit is operated in the continuous or pulsed mode during the placement of the catheter. The clinical situation for which the exposure information is applicable and the geometrical location of the entrance skin relative to the x-ray source is to be indicated.

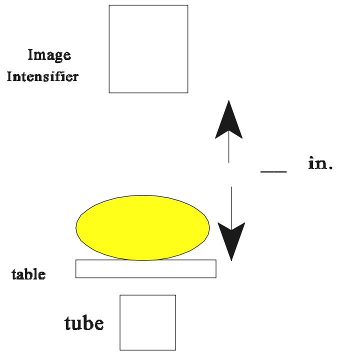
Example formats deemed acceptable to the Division are included. (Note: The Division recognizes that other formats are possible which would meet the intent of the regulations.)

Example 1: A fluoroscopic unit is used in a cath lab. It has “normal” and “pulsed normal” ABC modes. During the placement of the catheter, the normal ABC mode is used. The unit has a digital recording system and during the injection of the contrast agent, the unit is used in the pulsed mode and images recorded at 30 frames per second. The unit is used in an under table configuration.

X-ray Unit: ____________________
Date: ____________

Entrance Skin Exposure Rate (mR/min)
at the table top; continuous mode
mA

| | | ---- | ---- | ---- | ----- |
|---|---|---|---|---|---|
| | ---- | | | | |
| kVp | ---- | | | | |
| | ---- | | | | |
| | ---- | | | | |
| | | | | | |

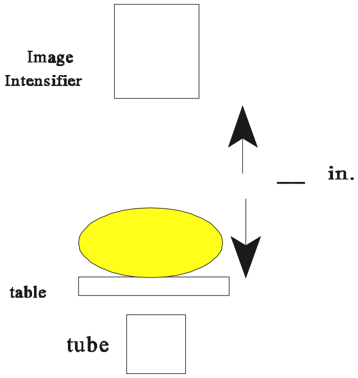


Example 2: The fluoroscopic unit is used in a cath lab. The unit has several ABC modes and can be operated in either a continuous or pulsed mode. The recording mode is a cine camera. The unit is only used in an ABC pulsed mode. The cine recording is at 15 or 30 frames per second. The x-ray equipment is used in both under table and lateral geometrical configurations.

X-ray Unit: ____________________
Date: ____________

Entrance Skin Exposure Rate (mR/min)
at the table top; pulsed mode
mA

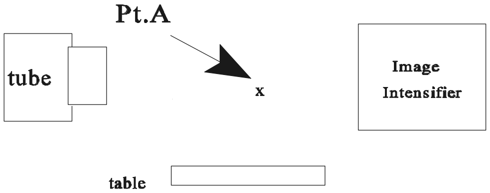
|  |  | ---- | ---- | ---- | ----- |
|---|---|---|---|---|---|
|  | ---- |  |  |  |  |
| kVp | ---- |  |  |  |  |
|  | ---- |  |  |  |  |
|  | ---- |  |  |  |  |
|  |  |  |  |  |  |



X-ray Unit: ____________________
Date: ____________

Entrance Skin Exposure Rate (R/min)
@ pt. A; pulsed mode
mA

|  |  | __ | __ | __ | __ |
|---|---|---|---|---|---|
|  | ___ |  |  |  |  |
| kVp | ___ |  |  |  |  |
|  | ___ |  |  |  |  |
|  | ___ |  |  |  |  |
|  |  |  |  |  |  |



pt. A is ____ cm. from the x-ray source